Consent Form Considerations

- Gene therapy products may be associated with a risk of potential germ line alterations

- Subjects should be informed of this risk

- Regulatory:
  - 1) Requirements
  - 2) Expectations
  - 3) Requests

Consent Form Considerations

- **1) Requirements for sponsor:**

"A commitment (form 1571) that an Institutional Review Board..will be responsible for the initial and continuing review and approval of each study…"

•2) Expectations of IRB:

"An IRB shall require that information given to subjects is in accordance with 21 CFR 50.25…"

"The information given to the subject shall be in a language understandable to the subject…including a description of any reasonably foreseeable risks…"

- **3) Request of sponsor: Consent form**
  - *"Risks associated with treatment in this study include the possibility of permanent genetic alterations in some of your sperm (men) or eggs (women). Some of these changes could lead to miscarriage or abnormalities in your children. Other changes may have no apparent effects but could still be passed on to future generations. These changes could be neutral or may eventually cause abnormalities. The likelihood of such outcomes is currently unknown."*